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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,661	11/14/2003	David L. Thompson	P-4334.05	9845

27581 7590 02/21/2008

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EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
02/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

CT

Office Action Summary	Application No.	Applicant(s)	
	10/713,661	THOMPSON ET AL.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/3/07 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 43-48, 51 and 52 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pfeiler et al (5558640).

Pfeiler shows the first medical device 9, with memory, 4, and telemetry unit 8, and second medical device, 11, with telemetry unit 12, connected to each other through telemetry either through programmer, 15, or directly (e.g. col. 5, line 2). Pfeiler also discloses the use of sensor calibration information (e.g. col. 4, line 4) and using the sensor information to operate the second implantable device in an optimized, compatible operation (e.g. col. 3, line 1, col. 4, line 44, etc). The sensor itself can be considered the optional component since the system could operate in an open loop fashion and the second device is disabled if the sensor indicates that the dosing unit need not deliver a dose of insulin. It is inherent that the calibration data is stored and that the calibration data is used for configuring the second IMD since the data must be remembered/stored somehow in order to transmit it and since calibration data is used to calibrate the sensor signals to get an accurate sensor reading for dosing.

In the alternative, Pfeiler discloses the claimed invention and method, but does not disclose that the calibration data is stored in the first medical device and used to configure the second medical device and the first device containing an optional component. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical device system/method as taught by Pfeiler, with the calibration data being stored in the first medical device and used to configure the second medical device, and the use of an optional component in the first device, since it was known in the art that medical device systems

and methods use calibration data that is stored in the first medical and used to configure the second medical device in order to provide the predictable results of a system/method that continually stores the calibration data for use in correcting/calibrating the first medical device's data and can continually be sent to other devices and used to configure the second device so that the second medical device can configure itself precisely based on the calibration data in order for the second device to operate correctly. In addition, it was known in the art for the first device to contain optional components, such as other sensors, since it was known that medical device methods use other optional components in a first medical device to provide the predictable results of allowing more data to be sensed to base the operation of the second medical device.

Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfeiler. Pfeiler discloses the claimed invention and the use of a third medical device (e.g. 15) being configured based on data from the second medical device, but does not disclose powering of the first communication circuit by a signal from the second communication circuit and the third medical device being implantable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical device and system as taught by Pfeiler, with the powering of the first communication circuit by a signal from the second communication circuit, and making the third medical device implantable since it was known in the art that medical device systems and methods use: a powering of a first communication circuit by a signal from the second communication circuit to provide the predictable results of allowing the first medical device to use less power and be of a smaller size/footprint since a smaller battery or no battery is needed; and making the third medical device implantable to provide the

predictable results of allowing the system to be completely implantable and automatic and allowing the patient to live a normal life without being burdened with external devices.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lebel, Lesho, Jackson, and Quinn are several examples of many showing the use of implantable medical device stored calibration data to configure a second medical device. In addition, the previous cited Schulman is one example of many showing the use of the third device being implantable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762

2/18/8

GRE
2/18/08